UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRACI REILLY, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, et al., Defendants.	:	Honorable Madeline Cox Arleo Civil Action No. 07-4665 (SDW) **REPORT AND RECOMMENDATION**

This matter comes before the Court upon the motion of plaintiff, Traci Reilly ("plaintiff"), to remand the pending matter to the Superior Court of New Jersey. Defendants Novartis Pharmaceuticals Corporation ("Novartis") and Astellas Pharma US ("APUS") (sometimes collectively "defendants") oppose the motion to remand on the grounds that plaintiff's claim for punitive damages under the New Jersey Product Liability Act, N.J.S.A. § 2A:58C-1, et seq. ("NJPLA") raises a federal question. (Dkt. Entry No. 30).

District Judge Wigenton referred plaintiff's motion to me for a Report and Recommendation. For the reasons set forth below, it is respectfully recommended that plaintiff's motion to remand be **GRANTED**.

Background

On September 14, 2007, plaintiff filed this action in the Superior Court of New Jersey, Essex County, seeking damages for bodily injuries allegedly caused by using the Elidel product

of Novartis and co-defendants Novartis Pharma GMBH and Novartis AGl, and the Protopic product of Astellas and co-defendant Astella Pharma Inc., to treat her eczema.[1] According to the complaint, both the removing and non-removing defendants' conduct regarding the design, manufacture, distribution, marketing and promotion of Elidel and Protopic violated the NJPLA, New Jersey's Consumer Fraud Act, N.J.S.A. § 56:8-1 et seq. ("NJCFA"), and New Jersey common law. Plaintiff's claims include: (1) failure to warn under the NJPLA, (2) breach of express warranty, (3) violation of the NJCFA, (4) breach of implied warranty under the NJPLA, (5) defective design under the NJPLA, and (6) punitive damages under common law and the NJPLA.

On September 28, 2007, Novartis and APUS removed the matter to federal court. They argue that plaintiff's claims for punitive damages under the NJPLA and NJCFA raise a federal question because she asserts that all defendants intentionally withheld information from the Federal Food and Drug Administration ("FDA"). On November 11, 2007, plaintiff filed a motion for remand, which Novartis and APUS opposed. By order dated April 15, 2008, the Court dismissed the motion without prejudice to refile, and stayed the case pending the resolution of Wyeth v. Levine, 555 U.S. __, 129 S. Ct. 1187 (2009).[2]

On April 16, 2009, Judge Wigenton issued a Consent Order, lifting the stay in light of the Wyeth decision. On April 27, 2009, plaintiff refiled her remand motion. She argues that the

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[1] A review of the official docket reflects that Defendants Novartis Pharma GMBH, Novartis AG, and Astella Pharma Inc. have not entered appearances in this case.

[2] Wyeth involved the issue of whether the FDA's remarks could be used as evidence that state law failure to warn claims "would obstruct the purposes and objectives of federal drug labeling regulation." 555 U.S. at ___, 129 S. Ct. at 1199. The Supreme Court found that the FDA's remarks did not warrant any deference. Id. at 1203.

Court should remand the case because: (1) no federal question is presented on the face of plaintiff's well-pleaded complaint; (2) defendants have not demonstrated that plaintiff's NJPLA failure to warn claim or punitive damages claim under the NJPLA raise a "disputed and substantial" federal issue; and (3) federal jurisdiction of these two claims would upset the state and federal balance.[3] Defendants, on the other hand, contend that because the NJPLA requires proof of a violation of FDA regulations to recover punitive damages, plaintiff's NJPLA punitive damages claim raises federal issues warranting federal jurisdiction.[4]

Legal Standard for Removal

As a preliminary matter, a district court has subject matter jurisdiction to hear claims "arising under the Constitution, laws, or treaties of the United States," pursuant to 28 U.S.C. § 1331. A claim brought in state court may be removed to federal court under 28 U.S.C. § 1441. A party may seek to remand a civil action back to state court based on an alleged defect in the removal procedure, or lack of subject matter jurisdiction. 28 U.S.C. § 1447(c). A party opposing remand must show that removal was proper. Boyer v. Snap-On Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990), cert. denied, 498 U.S. 1085 (1991). The Third Circuit has held that "the party asserting federal jurisdiction in a removal case bears the burden of showing, at all stages of the litigation, that the case is properly before the federal court." Frederico v. Home Depot, 507 F.3d 188, 193 (3d Cir. 2007) (citing Samuel-Bassett v. KIA Motors Am., Inc., 357 F.3d 392, 396 (3d

[3] In her moving brief, plaintiff states that she is no longer pursuing her NJCFA claim, and thus, the Court need not reach the merits of removal based on this claim.

[4] In opposition to remand, defendants rely solely on the NJPLA punitive damages claim as the purported basis for federal question jurisdiction, arguing it is the threshold issue. As defendants do not argue the merits of the NJPLA failure to warn claim as a sufficient basis for federal question jurisdiction, the Court does not reach the merits of any such argument.

Cir. 2004)). Thus, the Court must analyze whether the action was removable as pending in the state court. See 28 U.S.C. §§ 1441(a), 1446; see also United States Express Lines, Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002). Courts must narrowly construe section 1441 against removal. See Shamrock Oil & Gas Corp. v. Sheets, 313 U.S. 100, 108-09 (1941).

Typically, the pleading determines whether a complaint is subject to federal law. The Supreme Court has stated: "It is long settled law that a cause of action arises under federal law only when plaintiff's well-pleaded complaint raises issues of federal law." Metropolitan Life Insurance Co. v. Taylor, 481 U.S. 58, 63 (1987). The fact that plaintiff's state law claims may be preempted by federal law is insufficient to confer federal question jurisdiction. Dawson v. Ciba-Geigy Corp., 145 F. Supp. 2d 565, 568 (D.N.J. 2001). Thus, "removal is not proper if based on a defense or an anticipated defense which is federal in nature, even if both parties admit that the federal defense is the only real question in the case." Id.

At the outset, it is important to distinguish between "complete preemption" and "ordinary preemption." Although normally federal preemption does not permit removal, "in certain circumstances the preemptive force of federal law is so powerful that it completely displaces any state law cause of action, and leaves room only for federal law for purposes of the 'well-pleaded complaint' rule." Id. Thus, the doctrine of complete preemption permits removal of an action to federal court when: (1) a federal statute wholly displaces a state law cause of action and creates a superseding cause of action, and (2) there is a "clear indication of a Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law." Railroad Labor Executives Ass'n v. Pittsburg & Lake Erie R.R., 858 F. 2d 936, 942 (3d Cir. 1988). Thus, unless there is "complete preemption," a court must determine whether a case "arises under" federal law

sufficient to warrant removal.

Removal based on federal question jurisdiction is governed by the well-pleaded complaint rule which states that "arising under" jurisdiction exists only when a federal question is presented on the face of the complaint. Caterpillar Inc. v. Williams, 482 U.S. 386, 392 (1987). Thus, the well-pleaded complaint rule is satisfied whenever "federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." Franchise Tax Board v. Construction Laborers Vacation Trust, 463 U.S. 1, 27-28 (1983).

However, the "mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." Merrell Dow Pharmaceuticals Inc., v. Thompson, et al., 478 U.S. 804, 813 (1986). In Merrell Dow, the Supreme Court emphasized that the proper inquiry turns on whether the state action based complaint raises a substantial federal issue. Federal question jurisdiction exists if resolution of the substantial federal issue is necessary to the resolution of the pleaded state law claim. Id. at 804.

In Merrell Dow, the plaintiffs brought multiple state law claims, including a claim for negligence *per se*, against a pharmaceutical company. As part of that claim, plaintiffs alleged the defendant's failure to follow the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (hereinafter "FDCA"), amounted to a rebuttable presumption of negligence. In finding the defendant's removal of the action improper, the Supreme Court found that the plaintiffs' negligence action based in part on their allegation that the defendant violated a federal misbranding prohibition under the FDCA did not present a federal question. Id. at 807. The Supreme Court held that "a complaint alleging a violation of a federal statute as an element of a

state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under' . . . [§1331]." Id. at 817.

More recently, in Grable & Sons Metal Products, Inc. v Darue Engineering & Manufacturing, the Supreme Court clarified its holding in Merrell Dow and view of "arising under" jurisdiction. 545 U.S. 308 (2005). The Court explained that federal jurisdiction may be proper over state law claims if "it 'appears from the [complaint] that the right to relief depends upon the construction or application of [federal law].'" Id. at 313 (internal citation omitted). Thus, Grable posed the following question:

> [D]oes a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.

Id. at 314. Thus, two prongs must be satisfied under Grable to determine if an issue presents a federal question: (1) the state law claim must "necessarily raise a stated federal issue," and (2) federal jurisdiction must not upset the "balance of federal and judicial state responsibilities." Id. In other words, to find that a state-law claim implicates significant federal issues, the federal interest at stake must be substantial. See id. The mere existence of a federal issue in a state law cause of action does not automatically create federal question jurisdiction. See id.

The Court further limited the situations where purely state law claims embedded with a federal issue may create "arising under" jurisdiction in Empire Healthchoice Assurance, Inc. v. McVeigh. 547 U.S. 677 (2006). In Empire, the Court narrowly construed its holding in Grable to establish a "special and small category" of federal jurisdiction. 547 U.S. at 699. In this category federal jurisdiction will stand only when the federal interest at stake is substantial

enough to "warrant turning [a state-law claim] into a discrete and costly 'federal case'...." Id. at 701. The Court explained, "[I]t takes more than a federal element to open the arising under door." Id. (internal citation omitted).

Discussion

Here, there is no serious dispute that a federal question is not presented on the face of the well-pleaded complaint. A plain reading of the complaint makes clear that plaintiff seeks relief under New Jersey statutory and common law. Plaintiff does not seek relief under the FDCA or any other federal statute. Apparently acknowledging the gravamen of plaintiff's complaint, defendants instead rely on 28 U.S.C. § 1331, as interpreted by Grable, to assert federal question jurisdiction. Specifically, defendants contend that plaintiff's NJPLA punitive damages claim necessarily raises a substantial federal issue – whether Novartis and APUS violated FDA regulations – and exercising jurisdiction over this claim will not disturb the balance of duties between federal and state courts.

The Court begins by reviewing plaintiff's punitive damages claim under the NJPLA. Although the NJPLA imposes a ban on punitive damages for FDA-approved products, the statute provides an exception to the general rule if the plaintiff can demonstrate that the defendant knowingly misrepresented or withheld information from the FDA. N.J.S.A. § 2A:58C-5(c). That is what plaintiff alleges here – that defendants "misled the public and medical community regarding the safety of Elidel and Protopic." (Compl., ¶¶ 113-114). According to defendants, plaintiff make allegations that implicate federal law and regulations, such as the "FDA-approved labeling of Elidel and Protopic was inadequate, false, and misleading. . . [and that defendants] failed to appropriately amend or change the labeling for Elidel and Protopic." (Novartis Bf at 2-

2, APUS Bf at 2-3 (citing Compl., ¶¶ 2, 33-34, 42-43, 46-61, 65-66, 70-83, 91-95, 114-116, 130-133, 136-138)). Based on these specific allegations, defendants allege that this claim triggers federal question jurisdiction.

Recently, in Von Essen v. C.R. Bard. Inc., No. 06-4786, 2007 U.S. Dist. LEXIS 56311 (D.N.J. Jun. 18, 2007), this Court rejected a similar argument. Von Essen involved the plaintiff's punitive damages claim under the NJPLA for bodily injuries sustained from using the defendant's product – the Composix Kugel Hernia Patch.[5] Indeed, following this Court's decision in Von Essen, other judges in this district and others have uniformly rejected defendants' argument in support of "arising under" federal jurisdiction. See, e.g., Sullivan v. Novartis Pharm. Corp., 602 F. Supp.2d 527 (D.N.J. 2009); Sullivan v. Novartis Pharm. Corp., 575 F. Supp.2d 640 (D.N.J. 2008); Brown v. Organon Int'l Inc., No. 07-3092, 07-3456, 08-2021, 2008 U.S. Dist. LEXIS 55490 (D.N.J. Jul. 21, 2008); Fields v. Organon USA Inc., No. 07-2922, 2007 U.S. Dist. LEXIS 92555 (D.N.J. Dec. 12, 2007); DeAngelo-Shuayto v. Organon USA Inc., No. 07-2923, 2007 U.S. Dist. LEXIS 92557 (D.N.J. Dec. 12, 2007); In re Aredia and Zometa Prods. Liab. Litig., No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007).

Yet, defendants ask this Court to ignore these persuasive authorities, by finding that plaintiff's NJPLA punitive damages claim raises "arising under" federal jurisdiction. Defendants contend that plaintiff's claim relies on proving that defendants "knowingly misrepresented or withheld material or relevant information required to be submitted under FDA regulations."

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[5] Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, the Von Essen case was transferred under 28 U.S.C. § 1407 to the District of Rhode Island. On November 6, 2007, District Judge Mary Lisi adopted the undersigned's Report and Recommendation, and thus, granted the plaintiff's motion to remand the case to the Superior Court of New Jersey.

(Novartis Bf. at 5). Defendants maintain that determining whether they did, in fact, withhold from or misrepresent requisite information to the FDA implicates an intricate federal statutory and regulatory scheme. This Court disagrees.

Plaintiff's entitlement to punitive damages under the NJPLA does not depend on the resolution of a federal question sufficiently substantial to arise under federal law within the meaning of 28 U.S.C. § 1331. Indeed, plaintiff's NJPLA punitive damages claim parallels federal safety requirements and is premised on a duty between defendants, as manufacturers of the alleged defective product, and plaintiffs, as New Jersey consumers. Liability under the NJPLA rests exclusively on state law. The issue of punitive damages is not even reached until liability is established. If the trier of fact reaches plaintiff's claim for punitive damages under the NJPLA, the reviewing court must consider all relevant evidence, such as malice, materiality, causation and relevance. Such discreet findings by a state court do not implicate substantial federal issues. See Grable, 545 U.S. at 314; Merrell Dow, 478 U.S. at 814.

Whether proof of material misrepresentation or withholding of information from the FDA is an element of the NJPLA punitive damages claim, this Court finds that such issues are insufficiently substantial to confer federal jurisdiction. See Sullivan, 602 F. Supp.2d at 535; see also Von Essen, 2007 U.S. Dist. LEXIS 56311, at * 5. Therefore, Grable's first prong is not satisfied: the state law claim for punitive damages does not necessarily raise a substantial federal issue.

As to the second part of the Grable analysis, this Court is satisfied that expanding "arising under" jurisdiction for a state law tort action would disturb the "congressionally approved balance of federal and state judicial responsibilities." See Grable, 545 U.S. at 314. As

Magistrate Judge Campbell stated in analyzing this precise issue:

> Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. The object of the New Jersey legislature in creating this statute was to regulate and restrict when Plaintiffs could recover punitive damages, which falls squarely within its prerogative to regulate matters of health and safety. Where Plaintiffs seek punitive damages under the New Jersey statute in either state or federal courts and the issue of fraud-on-the-FDA is raised, the potential would exist for the FDA's personnel to be drawn into those controversy on a case-by-case basis over and over again. This would generate a wholly impractical solution.

In Re: Aredia and Zometa Products Liability Litigation, 2007 WL 649266, * at 11. See Sullivan, 602 F. Supp.2d at 537 ("[F]ederal jurisdiction over NJPLA punitive damages claims would markedly increase the volume of such cases in federal courts. . . . [T]his Court can discern no congressional intent to open the federal courts to the mass of state actions involving ethical drugs seeking punitive damages under the NJPLA.") The cases cited by defendants, which involve distinct factual predicates and legal theories as well as turn on the application and construction of federal statutes and/or intricate federal regulatory schemes, do not compel a different result. See, e.g., Pet Quarters, Inc. v. Depository Trust and Cleaning Corp., 559 F.3d 772, 779 (8th Cir. 2009); PNC Bank, N.A. v. PPL Elec. Utils. Corp., 189 F. App'x 101, 104 n.3 (3d Cir. 2006); Nicodemus v. Union Pac. Corp., 440 F.3d 1227, 1234-37 (10th Cir. 2006).

Morever, the statutory scheme designed by the New Jersey legislature embodies traditional tort law considerations and is not premised exclusively on federal disclosure requirements. The conduct must be proven by clear and convincing evidence and the material withheld must be "material and relevant to the harm...." N.J.S.A. § 2A:58C-5(c). Because plaintiff's claim rests almost entirely on traditional state tort law concepts, expanding "arising

under" jurisdiction here would infringe on an area traditionally left to the state. As such, under the second Grable prong, this Court could not serve as a proper federal forum for the instant case without disturbing "Congress's intended division of labor between state and federal courts." 545 U.S. at 319.

In support of defendants' position that the NJPLA punitive damages claim necessarily raises substantial federal issues, defendants rely on the finding in Buckman Co. v. Plaintiffs' Legal Comm., that claims alleging proof of fraud on the FDA implicate a significant federal interest. 531 U.S. 341, 352-53 (2001). In Buckman, the plaintiffs claimed that but-for the defendant's fraudulent statements to the FDA, the orthopedic bone screws at issue would not have been approved by the FDA, and the plaintiffs would not have been injured. The Court noted that the plaintiffs' state law fraud-on-the-FDA claims relied on the regulations of the Medical Device Amendments of 1976, 21 U.S.C. § 301 et seq. ("MDA") (as opposed to state law) as a critical element of their cause of action. The Supreme Court found that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Id. at 347. Such claims conflict with the MDA, and thus, they are preempted since the federal statutes empower the FDA, not individual consumers, to punish and defer fraud against the agency. Id.

The issue here is not, as defendants concede, whether there is Buckman preemption, but whether plaintiff's NJPLA punitive damages claim "arises under" federal law. See Grable & Sons Metal Prod. Inc, 544 U.S. at 311-12. See also Sullivan, 602 F. Supp.2d at 535. Thus, because Buckman addresses ordinary preemption, as opposed to "arising under" jurisdiction, it is not controlling on the jurisdictional issue before the court. Furthermore, notwithstanding

defendants' assertions to the contrary, "*Buckman* involved a specific cause of action for fraud-on-the-FDA, whereas the instant [Plaintiff] must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law." Sullivan, 575 F. Supp.2d at 652.

Conclusion

For the forgoing reasons, this Court respectfully recommends that plaintiff's motion to remand be granted.

The parties have ten (10) days from receipt hereof to file and serve objections.

s/Madeline Cox Arleo
MADELINE COX ARLEO
United States Magistrate Judge

Dated: July 28, 2009
Original: Clerk
cc: Hon. Susan D. Wigenton, U.S.D.J.
File